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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| EXAMINER |
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HARRIS, ALANA M

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| ART UNIT | PAPER NUMBER |
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1642

DATE MAILED: 01/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,281

Applicant(s)

GAUDERNACK ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24, 26-30, 33-56, 60 and 61 is/are pending in the application.
- 4a) Of the above claim(s) 26-29, 34 and 39-56 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 60 is/are allowed.
- 6) ☒ Claim(s) 24, 30, 33, 35-38 and 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendments and Arguments

1. Claims 24, 26-30, 33-56, 60 and 61 are pending.
 Claims 25, 31, 32 and 57-59 have been cancelled.
 Claims 26-29, 34 and 39-56, drawn to non-elected inventions are withdrawn from examination.
 Claims 24, 30, 33, 35-38 and 60 have been amended.
 Claim 61 has been added.
 Claims 24, 30, 33, 35-38, 60 and 61 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

3. The rejection of claim 31 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in light of the cancellation of the claim.

4. The rejection of claim 57 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the cancellation of the claim.

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Maintained and New Grounds of Rejection

Claim Rejections - 35 USC § 112

5. Claims 24, 30, 33, 35-38 and 61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION.**

Applicants have amended claim 24 to contain the recitation "said peptide containing up to 25 amino acids". Applicants note that support for this amendment can be found in paragraph 0036 of Applicants' specification, see Remarks submitted, page 11, fourth paragraph. The Examiner has reviewed this section of the specification and does not concur with Applicants. This section of the specification implicitly states that the telomerase peptide contains between 8 and 25 amino acids. This citation does not support peptides comprising less than 8 amino acids as embraced by the recitation, containing up to 25 amino acids. There is no support for peptides within the size range of 1-7 as embraced by the said recitation. Applicants should review the specification and are requested to pointedly express in the specification by page and line number where support can be located or delete the phrase.

6. Claims 24, 36-30, 33-56 and 61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in

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such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants broadly claim an isolated peptide capable of generating a T cell response directed against telomerase with the said peptide containing up to 25 amino acids and comprising SEQ ID NO: 2, as well as a multi-peptide composition comprising one of the said peptides in combination with at least one peptide not containing SEQ ID NO: 2. The written description in this instant case only sets forth a composition consisting of SEQ ID NO: 2, oncogene proteins or peptides (i.e. mutant p21-ras protein/peptide), tumor suppressor proteins (i.e. p53 and retinoblastoma (Rb)) and well known additives, diluents and stabilizers, see page 14, paragraph 0045; see page 15, paragraph 0045; and paragraphs 0075 and 0077 on pages 24-26. Applicants are not in possession of an isolated peptide comprising SEQ ID NO: 2 (16 amino acid residues) *and* arbitrary amino acids that are included in a single polypeptide. The remaining amino acids made mention to in the claims are uncharacterized, as well as undefined.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that[he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). Applicant is

reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Applicants are not required to disclose every species encompassed by a genus. For example as indicated in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Applicants are only in possession of a composition comprising the defined peptide, SEQ ID NO: 2 and oncogene peptides/proteins and tumor suppressor peptides/proteins and pharmaceutically acceptable carriers or diluents. Applicants are not in possession of unidentified and uncharacterized amino acids comprised within a single peptide with SEQ ID NO: 2. Claim 24 reads on a single peptide with SEQ ID NO: 2 and extraneous amino acid residues. Applicants are not permitted to claim all possible peptides including SEQ ID NO: 2 and unknown amino acids encompassed by the claims, hence are not entitled to the wide breadth of the claims at issue. As Applicants' claims are written they encompass variants, as well as sequences yet to be discovered. There is no description of the sites at which variability may be tolerated. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. One skilled in the art cannot reasonably

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conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

There is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645. Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 102

7. The rejection of claims 24, 30, 33 and newly added claim 61 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 6,166,178 (filed November 19, 1997) is maintained and made. Claims 25, 31, 32 and 57-59 have been cancelled.

Applicants argue "the amino acid sequences described in U.S. Patent No. 6,166,178...are all much longer than 25 amino acids", see Applicants' Remarks submitted, page 11, third paragraph. Moreover, Applicants suggest that they have obviated the instant rejection with the amendment of claim 24. Applicants' arguments and amendment have been carefully considered and reviewed but found to be unpersuasive.

Applicants' amendment to claim 24 includes the recitation, "said peptide *containing* up to 25 amino acids" which is regarded as open language, particularly the term, containing. The use of this language does not preclude additional amino acid

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residues added to the peptide. Consequently, the prior art of record meets the claim limitations and the instant rejection is maintained.

8. The rejection of claim 24 and newly added claim 61 under 35 U.S.C. 102(a) as being anticipated by Nakamura et al. (Science 277: 955-959, 15 August 1997/ IDS reference A3) as evidenced by Accession number O14783 is maintained and made. Claims 25 and 57-59 have been cancelled.

Applicants argue "the amino acid sequences described in...Nakamura et al. are all much longer than 25 amino acids", see Applicants' Remarks submitted, page 11, third paragraph. Moreover, Applicants suggest that they have obviated the instant rejection with the amendment of claim 24. Applicants' arguments and amendment have been carefully considered and reviewed but found to be unpersuasive.

Applicants' amendment to claim 24 includes the recitation, "said peptide *containing* up to 25 amino acids" which is regarded as open language, particularly the term, *containing*. The use of this language does not preclude additional amino acid residues added to the peptide. Consequently, the prior art of record meets the claim limitations and the instant rejection is maintained.

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9. The rejection of claim 24 and newly claim 61 under 35 U.S.C. 102(a) as being anticipated by Meyerson et al. (Cell 90: 785-795, 15 August 1997/ IDS reference A2) as evidenced by Accession number O14783 is maintained and newly made. Claims 25 and 57-59 are cancelled.

Applicants argue "the amino acid sequences described in...Meyerson et al. are all much longer than 25 amino acids", see Applicants' Remarks submitted November 8, 2004, page 11, third paragraph. Moreover, Applicants suggest that they have obviated the instant rejection with the amendment of claim 24. Applicants' arguments and amendment have been carefully considered and reviewed but found to be unpersuasive.

Applicants' amendment to claim 24 includes the recitation, "said peptide *containing* up to 25 amino acids" which is regarded as open language, particularly the term, containing. The use of this language does not preclude additional amino acid residues added to the peptide. Consequently, the prior art of record meets the claim limitations and the instant rejection is maintained.

Claim Rejections - 35 USC § 103

10. The rejection of claims 24, 30, 33, 35-38 and newly added claim 61 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 6,166,178 (filed November 19, 1997), in view of Gaudernack (Immunotechnology 2: 3-9, 1992/ IDS reference A6) is maintained and newly made. Claims 25, 31, 32 and 57-59 have been cancelled.

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Applicants aver they have obviated the 102(e) rejection and consequently the instant 103(a) rejection is moot. Applicants also assert that with the amendment to claim 24 the rejections have been obviated. These arguments and points of view have been carefully considered but found unpersuasive.

The rejection under 35 USC § 102 has been maintained for the reasons of record. Accordingly, the instant rejection under 35 USC § 103 is maintained and made.

11. The rejection of claims 24, 30, 33, 35-38 and newly added claim 61 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 6,166,178 (filed November 19, 1997), in view of Nijman et al. (Immunology Letters 40: 171-178, 1994) is maintained and made. Claims 25, 31, 32 and 57-59 have been cancelled.

Applicants aver they have obviated the 102(e) rejection and consequently the instant 103(a) rejection is moot. Applicants also assert that with the amendment to claim 24 the rejections have been obviated. These arguments and points of view have been carefully considered but found unpersuasive.

The rejection under 35 USC § 102 has been maintained for the reasons of record. Accordingly, the instant rejection under 35 USC § 103 is maintained and made.

Allowable Subject Matter

12. Claim 60 is allowed.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 6:30 am to 5:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER



Alana M. Harris, Ph.D.
13 January 2004